REMARKS

Examiner Interview Summary

Applicant thanks Examiner Saucier for the opportunity to discuss aspects of this case in a telephonic interview with Applicant's Representative Thomas W. Leffert on Monday May 12, 2003. Applicant notes that only the claim limitation "topical ophthalmic application" was discussed. Specifically, Applicant noted that the Office Action appears to equate intraocular application with topical ophthalmic application. Applicant contended that intraocular application refers to injection of the medicament within the interior of the eye. Applicant further contended that there is no support that injection within the eye would inherently produce the same effect as a topical ophthalmic application, i.e., an application to the exterior of the eye. The Examiner requested that Applicant point out this difference in a response to the Office Action.

Applicant believes the foregoing Summary accurately reflects the substance and scope of the telephonic interview of May 12, 2003. Applicant requests notification if the Examiner disagrees with the accuracy or completeness of the Summary.

Extrinsic References

Applicant notes that certain extrinsic references have been cited within this response to support Applicant's contention that topical ophthalmic application differs from intraocular application in response to the request by the Examiner during the Examiner Interview of May 12, 2003. Because these references are used in support of Applicant's position, and thus neither establish a *prima facie* case of unpatentability of a claim, nor refute a position the Applicant takes in opposing an argument of unpatentability relied on by the Office or asserting an argument of patentability, Applicant does not believe an information disclosure statement is required under Rule 56. Applicant is, however, enclosing courtesy copies of the cited references for the Examiner's convenience.

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Rejections Under 35 U.S.C. § 103

Claims 1-10 were rejected under 35 U.S.C. §103(a) as being unpatentable over International Patent Application WO 99/11242. Applicant respectfully traverses.

Claim 1 recites application of the medicament via topical ophthalmic application. The Office Action appears to equate intraocular application with topical ophthalmic application. Applicant contends that this is an improper characterization of the application routes. Applicant respectfully submits that the term intraocular refers to injection of the medicament within the interior of the eye. *See, e.g.,* McGraw-Hill Dictionary of Scientific and Technical Terms, Fifth Edition, 1994 ("intraocular [ANAT] Occurring within the globe of the eye."). *See also,* U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, Center for Drug Evaluation and Research, Information Management Team, Drug Registration and Listing Instructions (distinguishing between intraocular and ophthalmic routes of administration); WCC Standard Classification of Routes of Administration (distinguishing between intraocular administration of a medicament to the eye and ocular administration of a medicament upon the eyeball). Applicant contends that the topical ophthalmic application as recited in claim 1 and used in the Specification is limited to application of the medicament to an anterior surface of the eyeball. Applicant thus contends that topical ophthalmic application is a patentably distinct administration route over intraocular administration.

The Office Action states, "Patients administered the composition of example 2, page 8, intraocularly (abstract) would obtain the benefit as an inherent result of the method." Office Action, page 2. The Examiner has the burden of providing a rationale or evidence tending to show inherency. *See* MPEP § 2112; Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) ("In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.") (emphasis in original). Applicant contends that there is no support for the assertion that the benefits of a topical ophthalmic application, i.e., application to an anterior surface of an eyeball, of coenzyme ubiquinone Q10 would necessarily flow from the mere mention of coenzyme ubiquinone Q10 administered to the interior of the eye. Accordingly, Applicant contends that claim 1 is

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patentably distinct from the cited reference. As claims 2-10 depend from and further define patentably distinct claim 1, these claims are also believed to be allowable. Applicant thus respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a), and allowance of claims 1-10.

Allowable Subject Matter

Claims 11-13 were objected to as being dependent upon a rejected base claim, but were indicated to be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. However, Applicant contends that it has shown claim 1 to be patentably distinct from the cited reference. As claims 11-13 depend from and further define patentably distinct claim1, these claims are believed to be allowable without amendment to independent form. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the objection, and allowance of claims 11-13 in their present form.

CONCLUSION

In view of the above remarks, Applicant respectfully submits that the claims are in condition for allowance and requests reconsideration of the application and allowance of all pending claims.

If the Examiner has any questions or concerns regarding this application, please contact the undersigned at direct dial (612) 312-2204.

Respectfully submitted,

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